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IN THE UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

Dental Recycling North America, Inc.,

Plaintiff,

V.

Stoma Ventures, LLC,

Defendant.

Case No: 4:23-CV-00670

<u>DEFENDANT STOMA VENTURES, LLC'S ANSWER TO PLAINTIFF'S SECOND</u> <u>AMENDED AND SUPPLEMENTAL COMPLAINT</u>

COMES NOW Defendant Stoma Ventures, LLC ("Stoma"), by and through its undersigned counsel, and for its Answer to Plaintiff Dental Recycling North America, Inc.'s ("Plaintiff") Second Amended and Supplemental Complaint ("Complaint") states as follows:

NATURE OF THE ACTION

- Stoma admits that this purports to be an action directed to alleged false advertising and unfair competition asserted under the Lanham Act and Missouri common law. Stoma denies the substance of the alleged claims and denies that Plaintiff is entitled to any of the relief sought herein.
- 2. Denied.

PARTIES

- 3. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 3 of the Complaint and therefore denies the same.
- 4. Stoma admits that it is a limited liability company organized under the laws of Missouri with a place of business at 458 Whitestone Farm Drive, Chesterfield, Missouri 63017. Except as so expressly admitted, Stoma denies the allegations of Paragraph 4.

JURISDICTION AND VENUE

- 5. Stoma admits that this action purports to be brought under the Lanham Act, but Stoma denies the substance of the alleged claims or that Plaintiff is entitled to any of the relief sought herein. Stoma admits that this Court has subject matter jurisdiction over this action. Except as so expressly admitted, Stoma denies the allegations of Paragraph 5.
- 6. Stoma admits that venue is proper in this District and that Stoma is subject to personal jurisdiction in this District. Except as so expressly admitted, Stoma denies the allegations of Paragraph 6.
- 7. Stoma admits that this Court has personal jurisdiction over it. Except as so expressly admitted, Stoma denies the allegations of Paragraph 7.

FACTS PERTAINING TO PLAINTIFF'S CLAIMS

I. General and Introductory Allegations

- 8. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 8 of the Complaint and therefore denies the same.
- 9. With respect to the allegations contained in the first sentence of Paragraph 9, Stoma lacks knowledge and information sufficient to form a belief as to the allegations of the and therefore denies the same. Stoma admits the remaining allegations contained in Paragraph 9.
- 10. Admitted.
- 11. Admitted.
- 12. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 12 of the Complaint and therefore denies the same.
- 13. Stoma admits that amalgam removal devices may capture "amalgam" or filling materials

from a patient's mouth during use. The second sentence of Paragraph 13 is a legal conclusion, not a statement of fact, and to which no response is required. To the extent the second sentence contains any statement of fact, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 13.

- 14. Paragraph 14 represents a legal conclusion relating to uncited provisions of The Clean Water Act, which speaks for themselves as to their terms and contents and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the uncited provisions of the Clean Water Act, Stoma denies the same.
- 15. Paragraph 15 represents a legal conclusion relating to uncited "relevant EPA regulations," which speak for themselves as to their terms and contents and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the uncited "relevant EPA regulations," Stoma denies the same.
- 16. Paragraph 16 contains a legal conclusion relating to uncited "relevant EPA regulations," which speak for themselves as to their terms and contents and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the uncited "relevant EPA regulations," Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 16.
- 17. Stoma states that any EPA "published" material speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in anyway misrepresented or mischaracterized the uncited EPA "documents," Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 17.
- 18. Stoma states that the cited EPA publications speak for themselves as to their terms and contents, and to which no response is required. To the extent that Plaintiff has in any way

- misrepresented or mischaracterized the cited EPA publications, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 18.
- 19. Stoma states that the cited EPA publications speak for themselves as to their terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA publication, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 19.
- 20. Stoma states that the cited EPA publications speak for themselves as to their terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA publications, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 20.
- 21. Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 21.
- 22. Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 22 and therefore denies the same.
- 23. Stoma admits the Capt-all-branded product should be understood to be classified as "an amalgam removal device other than a separator" as provided in 40 C.F.R. § 441.30(a)(2). Except as so expressly admitted, Stoma denies the allegations of Paragraph 23.
- 24. Stoma admits the Capt-all-branded product should be understood to be classified as "an amalgam removal device other than a separator" as provided in 40 C.F.R. § 441.30(a)(2). Except as so expressly admitted, Stoma denies the allegations of Paragraph 24.
- 25. Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is required, Stoma lacks knowledge and information sufficient to form a belief as

- to the allegations of Paragraph 25 of the Complaint and therefore denies the same.
- 26. Stoma admits that the Capt-all-branded device is designed to be fitted on the end of an HVE (high volume evacuator) valve. Except as so expressly admitted, Stoma denies the allegations of Paragraph 26.
- 27. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 27 of the Complaint and therefore denies the same.
- 28. Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 28.
- 29. Denied.
- 30. Denied.
- 31. Denied.
- 32. Stoma admits that it updated advertising materials identifying that the Capt-all-branded products are best understood to be classified as "an amalgam removal devices other than a separator" as provided in 40 C.F.R. § 441.30(a)(2). Except as so expressly admitted, Stoma denies the allegations of Paragraph 32.
- 33. Stoma admits that it uses common adverting efforts to promote its products. Except as so expressly admitted, Stoma denies the allegations of Paragraph 33.
- 34. Stoma admits that it uses common adverting efforts to promote its products and that it has endeavored to offer and sell various products to Schein, Darby, and Benco over time. Except as so expressly admitted, Stoma denies the allegations of Paragraph 34.
- 35. Denied.
- II. Defendant's False and Misleading Advertisements and <u>Promotions Made Before Plaintiff Complained to Defendant</u>
- 36. Denied.

- 37. Denied.
- 38. Denied.
- 39. Denied.
- 40. Denied.
- 41. Denied.
- 42. Denied.
- 43. Denied.
- 44. Stoma admits that it published a link on its website to a report authored by J.A. King. Except as so expressly admitted, Stoma denies the allegations of Paragraph 44.
- 45. Denied.
- 46. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 46 of the Complaint and therefore denies the same.
- 47. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 47 of the Complaint and therefore denies the same.
- 48. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 48 of the Complaint and therefore denies the same.
- 49. Denied.
- 50. Denied.
- 51. Stoma admits the J.A. King Report contains, among other things, the statement quoted in Paragraph 51. Stoma denies the remaining allegations contained in Paragraph 51 of the Complaint and specifically denies that the report was revised because of Plaintiff's complaints.
- 52. Stoma admits the J.A. King Report contains, among other things, the statements quoted in

- Paragraph 52. Except as so expressly admitted, Stoma denies the allegations of Paragraph 52.
- 53. Stoma admits that it published a link on its website to a report by Purves Environmental,
 Inc. Except as so expressly admitted, Stoma denies the allegations of Paragraph 53.
- 54. Stoma admits the Purves Report contains the statement quoted in Paragraph 54. Except as so expressly admitted, Stoma denies the allegations of Paragraph 54.
- 55. Stoma admits its website contains the statement quoted in Paragraph 55. Except as so expressly admitted, Stoma denies the allegations of Paragraph 55.
- 56. Stoma admits the Capt-all-branded product should be understood to be an "amalgam removal device other than a separator" as provided in 40 C.F.R. § 441.30(a)(2). Except as so expressly admitted, Stoma denies the allegations of Paragraph 56.
- 57. Denied.
- 58. Denied.
- 59. Denied.
- 60. Denied.
- 61. Admitted.
- 62. Stoma admits it posted the video at the link provided in Paragraph 62 of the Complaint.

 Except as so expressly admitted, Stoma denies the allegations of Paragraph 62.
- 63. Stoma admits it posted the video at the link provided in Paragraph 63 of the Complaint.

 Except as so expressly admitted, Stoma denies the allegations of Paragraph 63.
- 64. Stoma admits it posted the video at the link provided in Paragraph 64 of the Complaint.

 Except as so expressly admitted, Stoma denies the allegations of Paragraph 64.
- 65. Stoma admits it posted the video at the link provided in Paragraph 65 of the Complaint.

- Except as so expressly admitted, Stoma denies the allegations of Paragraph 65.
- 66. Stoma admits it posted the video at the link provided in Paragraph 66 of the Complaint.

 Except as so expressly admitted, Stoma denies the allegations of Paragraph 66.
- 67. Paragraph 67 is a definitional statement to which no response is required. To the extent a response is required, Stoma denies the allegations of Paragraph 67.
- 68. Denied.
- III. Defendant's False and Misleading Advertisements and Promotions Made After Plaintiff Complained to Defendants
- 69. Denied.
- 70. Paragraph 70 contains legal conclusions to which no response is required. To the extent a response is required, Stoma denies the allegations of Paragraph 70.
 - A. Defendant Continues to Make False and Misleading Claims That Its <u>Capt-all Product Is an Amalgam Separator</u>
- 71. Denied.
- 72. Denied.
- 73. Denied.
- 74. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 74 of the Complaint and therefore denies the same.
 - B. Defendant's Continuing False and Misleading Advertisements and Promotions Regarding Amalgam Removal Devices Other than Separators
- 75. Denied.
- 76. Denied.
- 1. Defendant's Capt-all Device Cannot Remove Dental Amalgam Solids from All Amalgam Process Wastewater
- 77. Paragraph 77 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 77.

- 78. Paragraph 78 contains legal conclusions to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 78.
- 79. Paragraph 79 contains legal conclusions to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 79.
- 80. Stoma states that the quoted passage of 40 C.F.R. § 441.30 speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA regulation, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 80.
- 81. Stoma states that the quoted passage of 40 C.F.R. § 441.20 speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA regulation, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 81.
- 82. Stoma states that the quoted passage of 40 C.F.R. § 441.30(a)(2) speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA regulation, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 82.
- 83. Stoma states that the quoted passage of 40 C.F.R. § 441.30(b) speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA regulation, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 83.
- 84. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 84 of the Complaint and therefore denies the same.
- 85. Stoma states that the EPA Frequently Asked Questions speak for itself as to its terms and

- contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA regulation, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 85.
- 86. Paragraph 86 contains legal conclusions to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 86.
- 87. Paragraph 87 contains legal conclusions to which no response is required. To the extent a response is required, Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 87 of the Complaint and therefore denies the same.
- 88. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 88 of the Complaint and therefore denies the same.
- 89. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 89 of the Complaint and therefore denies the same.
- 90. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 90 of the Complaint and therefore denies the same.
- 91. Stoma admits that the Capt-all device is designed to be fitted on the end of an HVE valve.

 Except as so expressly admitted, Stoma denies the allegations of Paragraph 91.
- 92. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 92 of the Complaint and therefore denies the same.
- 93. Denied.
- 94. Denied.
- 95. Denied.
- 96. Denied.
- 97. Stoma admits that the screenshot in Paragraph 97 of the Complaint appears to contain

- directions for use of the Capt-all-branded product. Except as so expressly admitted, Stoma denies the allegations of Paragraph 97.
- 98. Stoma admits that the screenshot provided in Paragraph 98 of the Complaint appears to contain directions for use of the Capt-all product. Except as so expressly admitted, Stoma denies the allegations of Paragraph 98.
- 99. Denied.
- 100. Denied.
- 101. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 101 of the Complaint and therefore denies the allegations in Paragraph 101.
- 102. Stoma admits the quoted passage appears in Stoma's Motion to Dismiss. Except as so expressly admitted, Stoma denies the allegations of Paragraph 102.
- 103. Paragraph 103 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations of Paragraph 103.
- 104. Denied.
- 105. Denied.
- 106. Denied.
- 107. Stoma admits it has a page on its website entitled "Capt-all® EPA Compliance Q and A."

 Except as so expressly admitted, Stoma denies the allegations of Paragraph 107.
- 108. Paragraph 108 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 108.
- 109. Paragraph 109 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 109.
- 110. Paragraph 110 contains a legal conclusion to which no response is required. To the extent

a response is required, Stoma denies the allegations contained in Paragraph 110.

2. Use of Defendant's Capt-all Device Does Not Comply with the Required Best Management Practices

- 111. Stoma states that the quoted passage of 40 C.F.R. § 441.30(b) speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA regulation, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 111.
- 112. Paragraph 112 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 112 of the Complaint.
- 113. Paragraph 113 contains legal conclusions to which no response is required. To the extent a response is required, Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 113 of the Complaint and therefore denies the allegations in Paragraph 113.
- 114. Stoma admits that the Capt-all-branded devices are designed to be fitted on the end of an HVE valve. Except as so expressly admitted, Stoma denies the allegations of Paragraph 114.
- 115. Denied.
- 116. Denied.
- 117. Stoma admits the quoted language appeared on advertising materials. Except as so expressly admitted, Stoma denies the allegations of Paragraph 117.
- 118. Paragraph 118 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 118.
- 119. Stoma states that the "Sample One-Time Compliance Report" speaks for itself as to its

terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the referenced "Sample One-Time Compliance Report," Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 119.

- 120. Stoma states that the "Sample One-Time Compliance Report" speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the referenced "Sample One-Time Compliance Report," Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 120.
- 121. Stoma states that the "Sample One-Time Compliance Report" speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the referenced "Sample One-Time Compliance Report," Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 121.
- 122. Stoma states that the "Sample One-Time Compliance Report" speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the referenced "Sample One-Time Compliance Report," Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 122.
- 123. Denied.
- 124. Stoma states that the "Sample One-Time Compliance Report" speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the referenced "Sample One-Time"

- Compliance Report," Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 124.
- 125. Paragraph 125 contains a hypothetical situation and a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 125.

3. Defendant's Capt-all Device Does Not and Cannot Comply with the EPA's Required 95% Removal Efficiency Standard

- 126. Stoma states that the quoted passage of 40 C.F.R. § 441.30(a)(2) speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the cited EPA regulation, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 126.
- 127. Paragraph 127 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 127.
- 128. Paragraph 128 contains legal conclusions to which no response is required. To the extent a response is required, Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 128 of the Complaint and therefore denies the allegations in Paragraph 128.
- 129. Denied.
- 130. Denied.
- 131. Paragraph 131 is based upon a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 131.
- 132. Denied.
- 133. Denied.
- 134. Stoma admits that the J.A. King and Purves Reports test results found amalgam capture

efficiency exceeding 95%. Except as so expressly admitted, Stoma denies the allegations of Paragraph 134.

- 135. Denied.
- 136. Denied.
- 137. Stoma states that the uncited "relevant regulation" speak for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the uncited "relevant regulation," Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 137.
- 138. Denied.
- 139. Denied.
- 140. Denied.
- 141. Denied.
- 142. Denied.
- 143. Denied.
- 144. Denied.
- 145. Denied.
- 146. Stoma states that the J.A. King Report speaks for itself as to its terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the J.A. King Report, Stoma denies the same. Except as so expressly admitted, Stoma denies the allegations of Paragraph 146.
- 147. Stoma states that the uncited "regulations" speak for themselves as to their terms and contents, and to which no response is required. To the extent that Plaintiff has in any way misrepresented or mischaracterized the uncited "regulations," Stoma denies the same.

Except as so expressly admitted, Stoma denies the allegations of Paragraph 147.

- 148. Denied.
- 149. Denied.
- 150. Stoma admits the quoted passage appears in the Purves Report. Except as so expressly admitted, Stoma denies the allegations of Paragraph 150.
- 151. Denied.

COUNT I LANHAM ACT FALSE ADVERTISING - 15 U.S.C. § 1125(a)

- 152. Stoma incorporates its responses to each of the foregoing paragraphs as though fully set forth herein.
- 153. Stoma admits the Capt-all product should be understood to be an "amalgam removal device other than a separator" pursuant to 40 C.F.R. § 441.30(a)(2). Except as so expressly admitted, Stoma denies the allegations of Paragraph 153.
- 154. Denied.
- 155. Denied.
- 156. Denied.
- 157. Denied.
- 158. Denied.
- 159. Denied.
- 160. Denied.
- 161. Denied.
- 162. Denied.
- 163. Denied.
- 164. Denied.

165.	Denied.
166.	Denied.
167.	Denied.
168.	Denied.
169.	Denied.
170.	Denied.
171.	Denied.
172.	Denied.
173.	Denied.
174.	Denied.
175.	Denied.
176.	Denied.
177.	Denied.
178.	Denied.
179.	Denied.
180.	Denied.
181.	Denied.
182.	Stoma admits its Capt-all Information Guide stated that "Capt-all is classified as an EPA
	Equivalent Device meeting all best management practices under the final ruling,
	441.30(a)(2)(i-iii)." Except as so expressly admitted, Stoma denies the allegations of
	Paragraph 182.
183.	Denied.
184.	Denied.

- 185. Denied.
- 186. Paragraph 186 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 186.
- 187. Paragraph 187 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 187.
- 188. Paragraph 188 contains legal conclusions to which no response is required. To the extent a response is required, Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 188 and therefore denies the allegations in Paragraph 188.
- 189. Denied.
- 190. Paragraph 190 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 190.
- 191. Denied.
- 192. Denied.
- 193. Denied.
- 194. Denied.
- 195. Denied.
- 196. Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 196 and therefore denies the allegations in Paragraph 196.
- 197. Denied.
- 198. Denied.
- 199. Denied.
- 200. Denied.
- 201. Denied.

- 202. Denied.
- 203. Denied.

COUNT II CONTRIBUTORY LANHAM ACT FALSE ADVERTISING – 15 U.S.C. § 1125(a)

- 204. Stoma incorporates its responses to each of the foregoing paragraphs as though fully set forth herein.
- 205. Denied.
- 206. Denied.
- 207. Paragraph 207 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 207.
- 208. Paragraph 208 contains legal conclusions to which no response is required. To the extent a response is required, Stoma lacks knowledge and information sufficient to form a belief as to the allegations of Paragraph 208 and therefore denies the allegations in Paragraph 208.
- 209. Paragraph 209 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 209.
- 210. Paragraph 210 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 210.
- 211. Denied.
- 212. Denied.
- 213. Denied.
- 214. Denied.
- 215. Stoma admits that the Capt-all products are advertised, promoted, sold, and distributed by the Distributors in interstate commerce. Except as so expressly admitted, Stoma denies the allegations of Paragraph 215.

- 216. Denied.
- 217. Paragraph 217 contains a legal conclusion to which no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 217.
- 218. Stoma admits that it sells Capt-all product to each of the Distributors. Except as so expressly admitted, Stoma denies the allegations of Paragraph 218.
- 219. Denied.
- 220. Denied.
- 221. Denied.
- 222. Denied.
- 223. Denied.
- 224. Denied.
- 225. Denied.
- 226. Denied.

COUNT III MISSOURI COMMON LAW UNFAIR COMPETITION

- 227. Stoma incorporates its responses to each of the foregoing paragraphs as though fully set forth herein.
- 228. Denied.
- 229. Denied.
- 230. Denied.
- 231. Denied.
- 232. Denied.
- 233. Denied.

COUNT IV INJUNCTION AGAINST THE CONTINUED SALE OF THE CAPT-ALL PRODUCTS

- 234. The Court dismissed Count IV, see Memorandum and Order, ECF No. 79 at 14, so no response is required. To the extent a response is required, Stoma incorporates its responses to each of the foregoing paragraphs as though fully set forth herein.
- 235. The Court dismissed Count IV, see Memorandum and Order, ECF No. 79 at 14, so no response is required. To the extent a response is required, Stoma denies the allegations contained in Paragraph 235.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

For further answer, and as an affirmative defense, Stoma states that the Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

For further answer, and as an affirmative defense, Stoma states that each of the purported claims set forth in the Complaint is barred by the doctrines of waiver, acquiescence, and/or estoppel.

THIRD AFFIRMATIVE DEFENSE

For further answer, and as an affirmative defense, Stoma states that Plaintiff's claims are barred by the doctrine of unclean hands.

FOURTH AFFIRMATIVE DEFENSE

For further answer, and as an affirmative defense, Stoma states that at all times, Stoma acted in good faith.

FIFTH AFFIRMATIVE DEFENSE

For further answer, and as an affirmative defense, Stoma states that all acts or statements

asserted by Plaintiff to be false or misleading represent non-actionable opinion.

SIXTH AFFIRMATIVE DEFENSE

For further answer, and as an affirmative defense, Stoma states that no actual consumer confusion has resulted from any of the complained of acts or statements and as such Plaintiff is not entitled to any requested injunctive relief.

SEVENTH AFFIRMATIVE DEFENSE

For further answer, and as an affirmative defense, Stoma states that Plaintiff's complained of injuries were not caused by any act or statement of Stoma.

EIGHTH AFFIRMATIVE DEFENSE

For further answer, and as an affirmative defense, Stoma states that adjudication of Plaintiff's allegations requires the Court to interpret agency regulation without first allowing the agency to do so first and as such are preempted.

WHEREFORE, Stoma prays for judgment as follows:

- (i) That the Plaintiff takes nothing by way of its Complaint;
- (ii) That the Complaint, and each and every purported claim for relief therein, be dismissed with prejudice.
- (iii) That Stoma be awarded its costs of suit incurred herein, including attorney's fees and expenses; and
- (iv) That Stoma be awarded such other and further relief that this Court deems just and proper.

Dated: October 16, 2023 Respectfully submitted,

/s/ Paul L. Smelcer
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Attorneys for Defendant Stoma Ventures, LLC

CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of October, 2023 I caused the foregoing to be filed electronically with the Clerk of the Court, and therefore served upon all counsel of record.

/s/ Paul L. Smelcer